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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,349	12/02/2003	Teresa Mujica-Fernaud	MERCK-2805	1371

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EXAMINER	
OWENS, AMELIA A	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,349	MUJICA-FERNAUD ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *22-24 and 28-33* is/are withdrawn from consideration.

5)☒ Claim(s) *1-7* is/are allowed.

6)☒ Claim(s) *8-21,25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

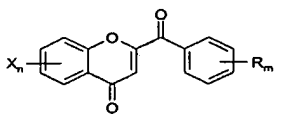
Claims 1-33 are pending. No drawings were filed. Foreign priority was claimed.

Election

Applicant's election with traverse of Group I, claims 1-7 in the reply filed on March 23, 2005 is acknowledged. The traversal is on the ground(s) that there is no undue burden. This is not found persuasive because the claims are related inventions for which clear evidence has been provided that they are different inventions and are independent and distinct under 802.01 since they have not been disclosed as combination and must be manufactured, used or sold a separate produces. Therefore, each and every invention is capable of separate manufacture, use or sale as claimed, and are patentable over each other. Thus, separate examination is required.

Claims 22-24, 28-29, 30-33 are held withdrawn as being directed to nonelected invention, 37 CFR 1.142(b).

Applicants' elected group I, compounds of formula I where the variables are as defined. Because the compounds were found allowable, the method claims 8-21, 25-27, were rejoined. *Claim 24 was not included as it was improperly grouped and should have been grouped with claim 22, containing an additional ingredient. Claim 30 was not included as it is directed to cosmetic of claim 29 and should have been grouped with claim 29.*



I

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-21,25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is various methods such as inhibiting tyrosine kinase, treating solid tumor, inhibiting angiogenesis, treating retinal vascularisation, etc. See claims 8-21, 25-27.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that

the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, 'solid tumor' include all forms of neoplasm that may metastasize and cause death. Certain class or types of compounds are known to treat certain type or class of solid tumors. Therefore, treating all form of 'solid tumor' known to man and yet to be discovered by man in wholly inoperable. It is unclear what the scope of 'inhibiting tyrosine kinase'; 'inhibiting angiogenesis'; 'treating a tyrosine kinase-dependent disease'; 'bone pathology'; 'inflammatory disease'; 'retinal vascularisation' is intended for. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to treat 'all' possible pathological conditions associated with the above conditions. Such language would allow applicant protection for future pathologies associated with these mechanisms that were not contemplated by applicant. Applicant cannot be allowed protection for that which applicant did not invent. 'Ocular disease' encompasses several conditions. Which particular 'ocular disease' are applicants treating?

The presence of working examples and guidance: A few compounds according to the invention have been made. Pharmacological tests at page 49 of the specification are noted. However, it is not seen how the test performed correlates to the various methods of use. The specification does not provide enablement for the treatment of the various diseases/conditions recited in the claims. For example, the test states that the compounds were tested as tyrosine kinase inhibitors. What exactly is the result of such inhibition? With what disease state/condition is such inhibition associated? Did the compound by inhibiting tyrosine kinase effective "treat" said disease state/condition? The specification does not make this clear? Nor is

there any evidence that the compounds are effective at any of the other methods – treating bone pathology, treating solid tumor for example.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

The use of the trademark on page 29 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

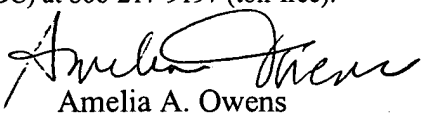
Allowable Subject Matter

The prior art neither teaches nor suggests the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens
Primary Examiner
Art Unit 1625